

ENSURING PROMPT, ACCURATE SPUTUM TESTING

GUIDELINE for ESTABLISHING EFFECTIVE POLICIES, PROCEDURES AND PRACTICES

This guideline has been developed by the Division of Public Health of the Department of Health and Family Services as a tool to assist local health departments in updating or developing policies, procedures and practices related to sputum specimens and results. It provides a model for the accurate collection and testing of sputum specimens for clients and patients in the jurisdiction of the local health department. It can be adapted according to each local health department's needs. In some sections, the local health department may be able to "fill in the blanks" to create their own documents. Items that provide additional information, education or reference are in italics or are otherwise set apart, such as in boxes. These portions are included for use during the adaptation process, are not written in policy and procedure language and are not required to be in the local health department's final policy or procedure documents.

Because it is not possible for any guideline or resource to address all potential situations for individuals, clinical judgement must always be exercised. All other legal requirements must be followed to ensure "due process" and all laws pertaining to minors and/or persons with guardians are to be followed when implementing this guideline.

When federal regulations, state statutes, administrative codes, Centers for Disease Control and Prevention (CDC) endorsed guidelines or standards of practice pertaining to tuberculosis are revised, the Division of Public Health will notify local health departments of the availability of these resources. Local health departments need to update their policies, procedures and practices accordingly to remain consistent with ongoing changes in legal requirements and tuberculosis care, for both the health of the affected individuals and the health of the public.

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- I. Terms and Definitions
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GUIDELINE for ESTABLISHING EFFECTIVE PRACTICE	Reviewed/Revised:
ENSURING PROMPT, ACCURATE SPUTUM TESTING	Signatures & Dates:

_____ Health Department	_____
Original Effective Date _____ Approved by _____	_____

GUIDELINE for POLICY DEVELOPMENT

I. Terms and Definitions:

Infection – The condition in which organisms capable of causing disease enter the body and elicit a response from the host’s immune system. TB infection may or may not lead to active TB disease, however persons with infection remain at life-long risk of developing active disease if their infection goes untreated. Also known as latent tuberculosis infection (LTBI).

Infectious tuberculosis – Tuberculosis disease of the respiratory tract, capable of producing infection or disease in others as demonstrated by the presence of acid-fast bacilli in the sputum or bronchial secretions or by chest radiograph and clinical findings.

Latent TB infection (LTBI) – Infection with *M. tuberculosis*, usually detected by a positive PPD skin test result, in a person who has no symptoms of active TB or radiographic evidence of active TB, and is not infectious. Tubercle bacilli are present in the body but the disease is not clinically active; same as TB infection.

Suspect tuberculosis – An illness marked by symptoms such as prolonged cough, prolonged fever, hemoptysis; compatible radiographic or medical imaging findings; or laboratory tests that may be indicative of tuberculosis. ***Suspected tuberculosis that is awaiting confirmation as either active tuberculosis disease or tuberculosis infection must be reported to the state or local health department.***

Symptomatic – Having symptoms that *may* indicate the presence of TB *or* another disease, such as cough, fever, night sweats, weight loss, hemoptysis, etc.

TB Case – A particular episode of clinically active TB. This is only used to refer to the disease itself, not the client with the disease. By law, cases of TB must be reported to the local health department as well as suspect tuberculosis as defined above.

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II. Purpose:

The purpose of this policy is to ensure that specimens for tuberculosis, particularly sputum specimens, are collected and tested promptly and accurately for all persons who are in the jurisdiction of the health department. This is necessary in order to ensure that persons with confirmed or suspected tuberculosis receive proper care and services and that the health of the public is protected. The local health officer, together with the local health department staff, are responsible for the education of public and private providers in order to ensure promptness and accuracy for the management of suspected and confirmed TB cases and the protection of the health of the public.

The person with active TB disease that is extrapulmonary requires the same public health services as the person with active pulmonary TB. However, once the possibility of the person with extrapulmonary TB *also* having pulmonary TB has been *completely* eliminated, a contact investigation is not indicated. **Except for the contact investigation, the treatment and case management of a person with active extrapulmonary TB and active pulmonary TB meet the same standards of practice.**

NOTE: "All TB control is local control." All TB prevention and control activities are the responsibility of the local health department. It is essential for the health department to ensure that specimens for tuberculosis in the jurisdiction of the health department are promptly and accurately collected, transported and tested. This is necessary in order to maintain standards and protocols for diagnosis and care of persons with confirmed or suspected tuberculosis and to protect the health of the public. This guideline serves as an adjunct to help the local health department meet their responsibilities and these standards of care.

III. Persons Affected/Responsible:

This policy will be carried out by _____ under the direction of
(List staff positions affected, not staff names)
the health officer of the _____ health department.
City/County

IV. Suggested Policy Language:

The _____ Health Department will ensure that specimens for tuberculosis testing for persons who are within the jurisdiction of the health department are collected, tested and reported promptly and accurately. The collection, submission and testing are to be done according to standard protocols established by the Centers for Disease Control and Prevention (CDC), the Wisconsin Department of Health and Family Service's TB Program and the Wisconsin State Laboratory of Hygiene. These protocols are addressed in the guideline "Accessing Services and Resources for Persons with Suspect or Active Tuberculosis Disease or Latent Tuberculosis Infection (LTBI)". The method for accessing this document from the Wisconsin TB Program Web Site is detailed in the appendix of this policy.

The health department will also follow subsequent, updated information published in notices or directives from the CDC, the Wisconsin TB Program, the Wisconsin State Laboratory of Hygiene or the Wisconsin State Epidemiologist. Specimen collection or testing will be provided or arranged for by the health department as indicated for a person's individualized TB case management. Consultation

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and technical assistance will be provided by the Wisconsin TB Program **when notification of the suspect or case has been received**. This consultation will include the review of the Wisconsin TB Program's Physician Consultant, when medically indicated, to preserve and protect the health of the individual and the public.

The person with extrapulmonary tuberculosis will receive all indicated public health communicable disease services. This includes ruling out pulmonary tuberculosis, directly observed therapy for those whose risk assessment for nonadherence identifies a need and the necessary ongoing monitoring for the emergence of pulmonary tuberculosis. This will include the services to populations in which extrapulmonary tuberculosis is more prevalent, particularly young children and the immunosuppressed.

The health department will provide specimen collection directly or, if arranged for by other providers, will ensure the prompt, accurate collection, handling and testing of these specimens. The health department will provide education, facilitate collaboration of public and private providers and maintain effective vigilance regarding sputum testing done in their jurisdiction. The health department may establish standing physician orders or may secure individual physician orders according to agency policy. Public health department staff should *collect* the specimen promptly when the person is able to produce sputum. The health department staff can then work within health department standing orders or with the individual physician for the documentation of orders for testing the specimen. Sputum specimens for TB control and surveillance that are authorized by the Wisconsin TB Program are tested at the Wisconsin State Laboratory of Hygiene under the physician authority of the Chief Medical Officer and State Epidemiologist for Communicable Diseases.

Whenever there is a breakdown in prompt, accurate specimen collection, testing or reporting within the jurisdiction of the health department, the health officer or designee will take the necessary steps to correct the problem and prevent it from recurring in order to protect the health of individuals and the public.

If a person who is suspected of active TB disease refuses to comply with the collection of specimens that are necessary for the evaluation of suspect or active TB disease, the person may be subject to isolation or confinement pursuant to s. 252.07(8) and (9), Wis. Stats., or to other and additional sanctions as the Court may determine. The Health Department will follow the statutes, codes, policies, procedures and practices for Isolation or Confinement as indicated to protect the health of the public.

V. Legal Authority:

The local health officer has authority under Wisconsin Statutes, Wis. Stats. ss. 252.07(8) & 252.07(9) and Wisconsin Administrative Code HFS 145.05 (1).

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VI. References Used for State Guideline Development

[The following references were used to develop the model state guideline. Any additional references used by the local health department should also be listed in the final policy document.]

1. American Thoracic Society and Centers for Disease Control and Prevention. **Diagnostic Standards and Classification of Tuberculosis in Adults and Children.** American Journal of Respiratory and Critical Care Medicine, April, 2000, 161:1376-1395.
2. American Thoracic Society/Centers for Disease Control and Prevention/Infectious Disease Society of America: **Treatment of Tuberculosis.** American Journal of Respiratory and Critical Care Medicine, 2003, Vol.167. pp 603-662. (Also published in **MMWR, June 20, 2003** / Vol.52 / No. RR-11)
3. Centers for Disease Control and Prevention. **Core Curriculum on Tuberculosis: What the Clinician Should Know.** Fourth Edition, 2000.
4. Centers for Disease Control and Prevention. **Targeted Tuberculin Testing and Treatment of Latent Tuberculosis Infection.** MMWR April, 2000;49 (No. RR-6).
5. Code of Federal Regulations (CFR) at 49 CFR Part 171.101, Part 173.134 and Part 173.199
6. National Tuberculosis Controllers Association. **Tuberculosis Nursing: A Comprehensive Guide to Patient Care,** 1997.
7. New Jersey Medical School National Tuberculosis Center. **Tuberculosis Glossary,** 1995
8. Wisconsin Department of Health and Family Services. **Wisconsin Administrative Rule, Control of Communicable Diseases,** Chapter 145.
9. Wisconsin State Laboratory of Hygiene Notice to Customers: Change in Shipping Requirements, 01-25-2003
10. Wisconsin Statutes, Communicable Diseases; ss. 252.07 – 252.10; 1999.
11. World Wide Web addresses, Wisconsin TB program, National Model TB Centers & CDC:

Wisconsin TB Program – www.dhfs.wisconsin.gov/dph_bcd/TB

Harlem Model Center – www.harlemtbcenter.org

New Jersey Model Center – www.umdnj.edu/ntbc

San Francisco Model Center – www.nationaltbcenter.edu

Centers for Disease Control and Prevention, CDC, Atlanta – www.cdc.gov/nchstp/tb

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GUIDELINE for PROCEDURE DEVELOPMENT

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II. Purpose:

The purpose of this procedure to provide specific instructions and resources that can be used to ensure that specimens for tuberculosis, particularly sputum specimens, are collected and tested promptly and accurately for all persons who are in the jurisdiction of the health department. It is crucial that the health department have the skills, abilities and resources to carry out these procedures so that TB, particularly respiratory TB, is promptly identified and that the policy related to sputum specimen testing is implemented. The health department will also use this procedure and these resources for the purpose of instructing others in prompt, accurate specimen collection, testing and reporting.

III. Persons Affected/Responsible:

This policy will be carried out by _____ under the direction of
(List staff positions affected, not staff names)
the health officer of the _____ health department.
City/County

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Suggested Procedure Language:

A. COLLECTION OF SPUTUM SPECIMENS

1. Follow established protocols and the direction of the Wisconsin Department of Health and Family Service's TB Program for the collection of sputum specimens. (See "Frequently Asked Questions about Sputum Specimens" in appendix.)
2. Follow agency policy regarding standing physician orders or collaborate with the individual's physician for orders for sputum specimen testing. *Collect* the specimen promptly, when the person is able to produce sputum, while working within health department standing orders or with the individual's physician for the documentation of orders for testing. Use the health department's fee exempt number.

NOTE: *Sputum specimens for TB control and surveillance authorized by the Wisconsin TB Program are tested at the Wisconsin State Laboratory of Hygiene under the authority of the Division of Public Health Chief Medical Officer and State Epidemiologist for Communicable Diseases.*

3. Obtain information on sputum specimen kits, Laboratory requisitions, transportation, timing and criteria for submission from the Accessing Services and Resources Guideline in Section C., Accessing Wisconsin State Laboratory of Hygiene (WSLH) Services.
4. Follow the directions for packaging, labeling and handling provided by the laboratory receiving the specimen and/or the manufacturer of the transportation materials.
 - a.) Regulations effective October 01, 2002 (for implementation in February & April 2003) for ground and mail transport of diagnostic specimens are in the Federal Register dated August 14, 2002. [Code of Federal Regulations (CFR) at 49 CFR Part 171.101, Part 173.134 and Part 173.199.]
 - b.) Follow the key points outlined in the Appendix entitled "Sender's Responsibility for labeling Transportation of Diagnostic Specimens". These instructions are based on the regulations effective 2002 that were implemented in 2003. Check with the laboratory to which the specimen will be sent about their submission and transportation criteria and keep up-to-date with any future regulation changes for transportation of biological specimens.
5. Follow infection control precautions and use personal protective equipment (PPE) as indicated by the clinical condition of the person. The minimum standard for respiratory protection for tuberculosis or suspected tuberculosis is an N-95 or higher, fit-tested respirator.
6. Collect early morning sputum specimens on three consecutive days, preferably Monday, Tuesday and Wednesday.
7. Collect specimens before eating, drinking or smoking so that sputum from the lung fields can be obtained. Saliva and mucus from the nose and throat are not acceptable. Inhaling steam (hot shower or boiling water) may help sputum production.
 - a.) Rinsing the mouth with water is advisable to minimize the resident flora in the mouth. However, if tap water in your area has abundant mycobacteria, such as *M. gordonae* or *M. avium*, sterile water is indicated. If necessary, this can be carried out in the home by boiling water along with a *heatproof*

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glass container for ten minutes, then cooling before use.

- b.) Teeth brushing with *water* is OK, but avoid an antiseptic solution such as mouthwash. Also consider potential water contamination as above and adjust accordingly.
8. **Provide supervised sputum collection for at least the first sputum specimen, until the person demonstrates the ability to properly collect the specimen.**
- a.) Persons who are suspected or confirmed as having TB can be so fearful of sputum specimen results that they will suppress a cough or even have another individual provide the specimen.
 - b.) **When results do not fit the clinical picture, supervision of specimen collection should be done to ensure that the health of the public is protected.**

NOTE: “Unsupervised patients are seldom successful in providing an adequate specimen, especially the first time. The amount of coaching required on later visits will depend on individual patient needs.” Core Curriculum on Tuberculosis, 4th Edition, 2000, p. 42

9. Refrigerate specimen if it is not immediately mailed or picked up by the courier.
10. Individualize the need for submission of sputum specimens according to clinical need. In general, sputum specimens that are indicated for patient care and monitoring are outlined in the DPH document “Frequently Asked Questions about Sputum Specimens”, included in the appendix. Additional questions can be answered by the Wisconsin TB Program at 608-266-9692.

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References Used for State Guideline Development

[The following references were used to develop the model state guideline. Any additional references used by the local health department should also be listed in the final policy document.]

1. American Thoracic Society and Centers for Disease Control and Prevention. **Diagnostic Standards and Classification of Tuberculosis in Adults and Children.** American Journal of Respiratory and Critical Care Medicine, April, 2000, 161:1376-1395.
2. American Thoracic Society/Centers for Disease Control and Prevention/Infectious Disease Society of America: **Treatment of Tuberculosis.** American Journal of Respiratory and Critical Care Medicine, 2003, Vol.167. pp 603-662. (Also published in **MMWR, June 20, 2003** / Vol.52 / No. RR-11)
3. Centers for Disease Control and Prevention. **Core Curriculum on Tuberculosis: What the Clinician Should Know.** Fourth Edition, 2000.
4. Centers for Disease Control and Prevention. **Targeted Tuberculin Testing and Treatment of Latent Tuberculosis Infection.** MMWR April, 2000;49 (No. RR-6).
5. Code of Federal Regulations (CFR) at 49 CFR Part 171.101, Part 173.134 and Part 173.199
6. National Tuberculosis Controllers Association. **Tuberculosis Nursing: A Comprehensive Guide to Patient Care**, 1997.
7. New Jersey Medical School National Tuberculosis Center. **Tuberculosis Glossary**, 1995
8. Wisconsin Department of Health and Family Services. **Wisconsin Administrative Rule, Control of Communicable Diseases**, Chapter 145.
9. Wisconsin State Laboratory of Hygiene Notice to Customers: Change in Shipping Requirements, 01-25-2003
10. Wisconsin Statutes, Communicable Diseases; ss. 252.07 – 252.10; 1999.
11. World Wide Web addresses, Wisconsin TB program, National Model TB Centers & CDC:

Wisconsin TB Program – www.dhfs.wisconsin.gov/dph_bcd/TB

Harlem Model Center – www.harlemtbcenter.org

New Jersey Model Center – www.umdnj.edu/ntbc

San Francisco Model Center – www.nationaltbcenter.edu

Division of Tuberculosis Elimination, CDC, Atlanta – www.cdc.gov/nchstp/tb

APPENDIX & RESOURCES

1. **Accessing Services and Resources Guideline** from the Wisconsin Tuberculosis Program Web Site
2. **Sender's Responsibility for labeling and Transportation of Diagnostic Specimens**
3. **Sample letter requesting physician orders for sputum specimens**
4. **Sample "standing orders" for collection of sputum specimens**
5. **Frequently Asked Question about Sputum Specimens**
6. Ordering information for **Conducting Sputum Induction Safely** booklet

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For details on sputum specimen submission and interpretation of results, go to the

Wisconsin TB Program Web Site:

www.dhfs.wisconsin.gov/dph_bcd/tb

On the TB Program's Home Page, scroll down and select the **Quick Link** to

**Guidelines for Establishing
Effective Policies, Procedures and Practice**

Scroll down the list of Guidelines for Effective Practice to

**Accessing Services and Resources for Persons with
Suspect or Active Tuberculosis or Latent Tuberculosis Infection**

select either the
PDF or WORD version of
the Guideline and go to Section C., page 63

Section C.

Accessing Wisconsin State Laboratory of Hygiene Services

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Sender's Responsibility for labeling and Transportation of Diagnostic Specimens - Effective 10-02-2002

(Note: the receiving laboratory can provide assistance and information. The sender retains responsibility, including for the training and the documentation of training for involved persons.)

Diagnostic specimen means any human or animal material, including excreta, secreta, blood and its components, tissue, and tissue fluids being transported for diagnostic or investigational purposes, but excluding live infected humans or animals.

- ❑ Triple packaging required: primary receptacle, secondary packaging and outer packaging
- ❑ Primary receptacle - packed in secondary packaging in such a way that, under normal transport conditions, they will not break, be punctured or leak; volume limit is 500 ml.
- ❑ Secondary packaging - leakproof, absorbent cushioning material between the primary receptacle and the secondary packaging sufficient to absorb the entire contents of the primary receptacle should it fail
- ❑ Exterior packaging - clearly and durably marked "**Diagnostic Specimen**"; package durable enough to drop 3.9 feet without breaking when packaging completed
- ❑ Outer packaging may not exceed four liters (one gallon) capacity
- ❑ Wisconsin State Laboratory of Hygiene Web Site

www.slh.wisc.edu

- ❑ For assistance contact the Wisconsin State Laboratory of Hygiene at
800-862-1088

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Sample Letter Requesting Physician Orders

Date: _____

Dear Dr. _____

In addition to your medical care, we are providing public health services to this client. According to the protocols of CDC and the Wisconsin TB Program, the specimens listed below are indicated for this person.

Indicating your concurrence on this form and forwarding it to us constitutes physician orders for the specimen collection and testing.

Call the public health contact person listed below for questions and to obtain information that will ensure prompt, accurate results. Specialized timing and transportation is required. Public Health can provide collection kits, requisition forms and instructions, including a complete guideline describing proper collection, exact timing, express transportation, and special instructions to the patient, the laboratory and to respiratory or nursing staff.

_____ **Health Department contact & phone number:** _____

Name of patient _____ Date of Birth _____

- ☐ Collect and submit **three, consecutive** early morning sputum specimens to the Wisconsin State Laboratory of Hygiene for
- ☐ AFB (Acid-fast Bacillus)
- ☐ **MTD (Mycobacterium Direct) [a rapid test that looks for the rRNA of *M. tuberculosis*]**
- ☐ Culture and Identification
- ☐ First Line TB Drug Sensitivities if culture positive

Physician's Signature _____ Date _____

Physician's Name _____ Phone number _____

Other information may be noted here if not previously known, submitted or documented:

Mantoux TB Skin Test (PPD) Date Applied _____ Date Read _____ Results (**induration only**) _____mm

- ☐ Contact to a current active TB case Specify: _____
- ☐ Medical risk factor Specify: _____
- ☐ Population risk factor Specify: _____

Chest X-ray: Date _____ Results: ☐ Normal ☐ **Abnormal**** ☐ **Abnormal but stable****

****Attach chest X-ray interpretation, if abnormal or abnormal but stable, if not previously submitted.**

The medications to treat TB disease or infection are available at no cost to the client. Public health services are indicated for everyone with TB disease or infection, *including those who are insured and financially stable*. Medical and TB Public Health services that are necessary to protect the health of the public must be provided regardless of the person's ability to pay. For clients without insurance for TB services, eligibility for the Medicaid TB-Related benefit or for general Medicaid will first be evaluated. For those who are uninsured or underinsured, the local public health department and the Wisconsin TB Program will provide follow up to attempt to identify a payor source.

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Sample Medical Standing Orders

(Note: This is an optional model - local health departments with effective policies/procedures/practices for standing orders may continue to use them.)

City/County **Health Department**

Standing Medical Order for the Collection of Sputum Specimens

With this medical order, I hereby authorize the collection of sputum specimens for the purposes of TB surveillance for persons who are within the jurisdiction of the health department. The collection of the necessary sputum specimens is part of the overall efforts of the above listed public health department to prevent and control *M. tuberculosis*.

This medical order authorizes the registered nurses and any trained designee to collect sputum specimens from persons in the jurisdiction of the above named health department. They are knowledgeable about all aspects of sputum specimen collection, transportation and testing and will follow the policies, procedures and practices for sputum specimen collection set forth by the above named health department. The most current statutes, rules, CDC guidelines and standards of practice relative to this activity will be followed.

Any reactions or untoward events that occur in the process of the collection of sputum specimens will be treated according to the emergency protocol established by the policies, procedures and practices of the health department and must be directly reported to me within 24 hours of occurrence. This order shall be reviewed as often as indicated, but at least on an annual basis.

Physician's Signature:

_____ Date _____

Printed Name of Physician

Medical Advisor, _____ Health Department
City/County

FREQUENTLY ASKED QUESTIONS on SPUTUM SPECIMENS

These are answers to frequently asked questions (FAQ's) regarding sputum specimens for the identification of tuberculosis for persons who are suspected or confirmed to have active respiratory tuberculosis disease. This information can be used by both public health and private health care providers for the diagnosis and care of these individuals. The information is consistent with the protocols of the Centers for Disease Control and Prevention (CDC) and the Wisconsin State Laboratory of Hygiene. It is based upon Wisconsin Statutes and Administrative Code requirements as well as the recommendations of medical experts in the treatment of tuberculosis and the statements of nationally recognized organizations. Because no guideline can address all possible circumstances, it is important to implement this information based on the comprehensive assessment of the person, their clinical condition, symptoms and accurate laboratory results. Expert physician consultation should be ensured when medically indicated. If you need additional information on legal reporting requirements, or this document does not answer your questions, contact the Wisconsin TB Program at 608-266-9692.

1. When should sputum specimens be collected?

These are the four most critical times for sputum collection. Further circumstances are described in the answers to questions five, six and seven.

- a.) To establish the **initial diagnosis** of *M. tuberculosis*
- b.) To **monitor** patient **infectiousness**
- c.) To **provide "proof of cure"** or efficacy of treatment by negative cultures
- d.) To **re-evaluate** potential **infectiousness** when treatment has been interrupted or inadequate.

2. Why does the state or local public health department need to be involved when sputum specimens are needed for identification of possible TB? Hospitals, laboratories and clinics collect and test sputum specimens all the time.

When the state or local public health department is notified of the possible suspicion of TB, they can authorize the **rapid testing of the sputum specimen** at the Wisconsin State Laboratory of Hygiene **for the rRNA of mycobacterium tuberculosis at no cost** to the provider or the patient, for both the insured person and those without insurance. With the state public health department authorization, physicians and health care providers can get prompt, accurate information **by the afternoon of the day the specimen arrives.*** This can help with decision-making, such as whether to continue or discontinue respiratory precautions and will assist with a prompt medical diagnosis. Twenty four-hour delivery services at no cost to the provider can also be authorized through the local public health department. Even though the process of "ruling out" TB may be ongoing, the obvious advantage of partnering with the local health department early is to ensure that the physician, the health care provider, the state and local public health department and the patient benefit from prompt, accurate sputum specimen results.

3. But the standard for confirming the medical diagnosis of TB is "culture identification". Why does a *suspect* who needs sputum specimens need to be reported? We are just checking sputum specimens; we don't know yet if they have TB.

Calling the health department to report that a person is ***suspected of tuberculosis*** satisfies the **legal requirement to report a TB suspect** and the health department can then **authorize transportation and payment for rapid sputum testing** while you are establishing a medical diagnosis.

* If a respiratory specimen for a person who has not been on medications for more than seven days is free of visible blood and is submitted to the Wisconsin State Laboratory of Hygiene within 24 hours of collection or within 72 hours of proper local processing, the specialized rapid test to look for TB rRNA (MTD test) can be performed **and the results will be available by 4:30 PM** the day the specimen is received.

FREQUENTLY ASKED QUESTIONS on SPUTUM SPECIMENS

The MTD test can be done “automatically” at the Wisconsin State Laboratory of Hygiene if the sputum is smear positive. The health department, in collaboration with the Wisconsin TB program, can authorize the Wisconsin State Laboratory of Hygiene to perform the MTD test even on a smear-negative respiratory specimen if deemed necessary because the person has signs and symptoms of tuberculosis and risk factors for exposure. Valuable days can be lost without this information if the health department does not get an early opportunity to facilitate this testing. Once the person is on TB medication for seven days, the test is not valid.

Calling the local health department with a verbal report of a *suspect* of tuberculosis satisfies the Wisconsin statutory and administrative code requirements for the reporting of suspects of a communicable disease. [Wis. Stats. 252.05, 252.07 (1m) and HFS 145.04(2)(b)] The **4151 form, “Acute & Communicable Disease Case Report”** can then be completed and sent by facsimile or mail. If TB is later ruled out, the local public health department will discharge the person from services unless they need treatment for latent TB infection (LTBI), or they have other health or family issues that require public health services.

4. What if the suspect is in the hospital in a negative pressure room with respiratory precautions and sputum specimens are being collecting? There is no risk to the health of the public when the person is hospitalized, so why would public health need to be called?

It is to the advantage of the patient and the provider to call and report the “suspect” status because the local health department can request an **authorization for payment** for the prompt **use of rapid TB sputum specimen testing** at the Wisconsin State Laboratory of Hygiene **even when the person is hospitalized**. This will help you make a rapid diagnosis or determination and may shorten hospitalization. Authorizing payment for services and testing from public funds when it is deemed necessary to protect the health of the public is a critical part of the public health mission because the **local health officer is held legally responsible for all tuberculosis control within their jurisdiction**. When a person is *suspected* of tuberculosis, the state or local health department has the ability to authorize payment from public funds for testing and services *even prior to confirmation of active disease if the person meets the suspect criteria*. This enables physicians and providers to make quicker determinations without concerns over the insurance status, to satisfy legal reporting requirements and to begin collaborating with the local public health for discharge planning.

The Wisconsin State Laboratory of Hygiene willingly collaborates with hospitals and other local and regional laboratories to ensure that the proper timing, transport and specimen processing is carried out so that the submitter is provided with the quickest and most accurate results. The exact logistics of these processes may vary according to the local laboratory procedures. The local health department and the Wisconsin State Laboratory of Hygiene will work together with the hospital or local/regional Laboratory to facilitate rapid and accurate testing of specimens.

5. What if the medical provider is still in the process of ruling out TB, but the person does not need acute hospital care? What sputum specimen results are needed to discharge them from the hospital or from respiratory precautions/isolation?

Discharging the person from the hospital and discontinuing airborne respiratory precautions (sometimes referred to as respiratory isolation) are **two different processes** and both require careful, collaborative determinations as described below.

- **Discharge from the hospital** requires partnering between the local public health department and the hospital, for detailed discharge planning, especially if the person is still infectious but seems medically stable. **The local public health department needs ample advanced warning to comprehensively evaluate the patient, the family and the living situation to determine if there are satisfactory living conditions for continuing respiratory isolation in the home.**

FREQUENTLY ASKED QUESTIONS on SPUTUM SPECIMENS

Increasingly, persons with suspect or active TB disease are homeless, which challenges the provider and the community to work together on a complicated discharge plan. These individuals are generally not appropriate for nursing home placement and the availability of negative pressure settings for continuing care is sparse. It is always advisable to plan ahead for the person still being infectious at discharge so that as many problems as possible are dealt with in advance. Most persons with active TB disease lead very complicated lives. The more advance warning the local public health department has, the more effective they can be in helping hospitals arrange for a satisfactory discharge plan and ensure that the health of the public is protected. Avoidance of prolonged hospitalization is everyone's goal.

- **Discontinuing respiratory precautions/isolation** requires a determination that the person is no longer infectious. This applies to both the person who is hospitalized and the person living in the community. **The local health officer is the person *ultimately responsible* for authorization of the release of a person from isolation or confinement in order to protect the health of the public.** When the person is hospitalized, the Infection Control Practitioner and the physician who is managing the medical care generally ensure that the implementation of respiratory precautions and the release from respiratory precautions meet the requirements and the standards of practice. The clearing of infectious status **varies greatly** from person to person. In order for the health officer to approve that a person be released from isolation, ***all of the following conditions are required to be met:*** [Reference - Wisconsin Administrative Code - HFS 145.11]

1. An adequate course of chemotherapy for a minimum of two weeks **and** clinical evidence of improvement.
2. Respiratory specimens that are free of acid-fast bacilli. The protocol is smear negative for three consecutive specimens collected on three different days, and
3. Specific arrangements have been made for post-isolation or post-confinement care and
4. The health officer considers the person not to be a threat to the health of the public and likely to comply with the remainder of the treatment regimen.

6. What should be done about the multiple medications the person must have after they go home?

The **discharge medication regimen** must meet the American Thoracic Society treatment protocols and be pre-authorized by the Wisconsin TB Program. Once the medication regimen is pre-authorized for payment, the local public health nurse picks up the medications promptly *from a local pharmacy*. The public health nurse then goes to the patient's home and initiates the patient's medication regimen, usually with directly observed therapy (DOT), the standard of care for active TB disease. The bond the local public health nurse case manager develops with the patient and family helps the patient adhere to the medication regimen for the full six months, or longer if indicated.

The Wisconsin TB Program authorization for billing goes by facsimile to the local health department, the public health nurse takes this to the pharmacy when picking up the medications and the dispensing pharmacy bills the TB program at the standard Wisconsin Medicaid rate. Medications for active disease, suspects, and high-risk close contacts are obtained promptly and locally in this manner, *not* from the central state medication supplier for less urgent LTBI clients where medications are mailed.

FREQUENTLY ASKED QUESTIONS on SPUTUM SPECIMENS

7. What about the cost of the rapid test? Many times a person being evaluated for TB has no health care insurance and no means to pay for care.

Clinical diagnosis of suspect or active TB disease must proceed promptly to protect health care workers and the health of the public in spite of any issues regarding funding sources. **The primary advantage of reporting a person to public health as a *suspect or* case of active TB disease, is that the state or local public health department may be able to arrange for rapid TB testing when the person meets the CDC and Wisconsin protocols for rapid testing. This will speed up the diagnostic process and generally save resources, particularly if days in respiratory isolation are shortened, regardless of the insurance status of the person.** *If* the patient and the specimen meet the CDC and Wisconsin protocols for authorizing rapid TB testing, the local public health department has the authority to arrange for fee-exempt testing at the Wisconsin State Laboratory of Hygiene. The local public health department becomes “the submitter” and public funds may be used for those without an insurance source to bill. Providers are still provided with prompt results. This process can be used even though the actual collecting, preparing and transporting of the specimen may be performed by a variety of persons and methods. **All persons who meet the criteria of a TB suspect *or* case are required to be reported to public health regardless of insurance status.** (See questions # 1. and # 2. on page one.) Insurance information is to be provided to the Wisconsin State Laboratory of Hygiene by the submitter for specimens from physician offices, clinics, laboratories or hospitals. Medicare, Medicaid and private insurance coverage can be utilized when persons are eligible *or can be presumed to be eligible*. In addition, the health department may authorize fee-exempt testing, regardless of insurance status, when indicated to protect the public from a potential or actual risk.

8. When is a sputum specimen needed during treatment for active TB disease?

This will vary according to what clinical questions need to be answered. Sputum smears, MTD tests and cultures are done to determine infectiousness and to establish a diagnosis. (See question one.) Use sputum testing whenever it is prudent to determine if there are tuberculosis organisms in the respiratory system and/or whether the person is infectious or non-infectious. **Use the algorithm for sputum determinations in the Accessing Services and Resources Guideline, Section C. for comprehensive information on interpreting and using sputum specimen results.****

Refer to the information on the tables on the next two pages for additional circumstances and explanations related to sputum specimens and the use of results.

FREQUENTLY ASKED QUESTIONS on SPUTUM SPECIMENS

This grid identifies *some* common clinical circumstances/times that indicate a need for sputum specimens. It is **not** all-inclusive; seek expert consultation for specific circumstances not addressed and/or call the Wisconsin TB Program. Clearing of organisms from sputum varies extensively from person to person. Persons who begin taking four TB medications often have to swallow a dozen or more pills. Prompt evaluation of accurate sputum results can reduce this, making adherence easier for the person. Example: Ethambutol can be discontinued once the person's organisms are confirmed to be sensitive to first-line TB drugs. PZA can be discontinued *after 8 weeks* for culture positive cases with confirmed sensitivity to first-line TB drugs or with clinical improvement, if the initial cultures returned negative.

Clinical Circumstances Involving Sputum Specimens & Monitoring	Sputum Specimen Results, Analysis & Considerations	Sputum Specimen Results, Analysis & Considerations
Initial determination of infectiousness or level of infectiousness	Smear Positive - Assume infectious <i>Mycobacterium tuberculosis</i> until proven otherwise without previous documented infection with non-TB mycobacteria*	Smear negative for three consecutive days <i>and</i> on treatment for two weeks, less likely to be infectious; evaluate entire picture
Initial determination was smear negative and treatment was <i>not started</i> , but patient was <i>later</i> found to be <i>culture positive</i>	Sputum that is initially smear negative can later grow <i>Mycobacterium tuberculosis</i> (can be six to eight weeks later, depending upon individual laboratory protocols)	If treatment was not begun, collect three "new" sputum specimens on three consecutive days to determine current infectious status. Three current, consecutive negative smears, <i>after two weeks on treatment</i> with clinical improvement to be <i>considered</i> not infectious. (Chest x-ray <i>may</i> be indicated; evaluate entire clinical picture.)
<i>After</i> two wks. of treatment, <i>with</i> clinical improvement, when initially Smear Positive - to establish if infectiousness is resolving	Recheck one sputum per week, in 2 nd or 3rd week. Smear Positive indicates still infectious. If initial organism burden high, consider decreased frequency to minimize patient disappointment.	Smear Negative - If negative one week, collect sputum for two more consecutive days. Three negative smears must be consecutive - no positive results in-between - to consider not infectious.
Initial identification of positive TB culture has been made on patient's specimens - monitoring of sensitivities is essential	All sputum specimens for culture are identified in the Wisconsin State Laboratory of Hygiene as TB or M.O.T.T. (mycobacteria other than tuberculosis) once sufficient growth is established	All positive TB cultures are set up for TB drug sensitivity to first-line TB drugs, 2 nd line if 1 st line resistance present. Sensitivity results take at least two weeks <i>after</i> being set up on culture growth.
When clinical improvement and/or chest xray improvement is established and the person has been on two months of therapy with TB medications to which the organisms are sensitive, sputum should be evaluated to determine clinical efficacy of treatment	Spontaneous or induced sputum is essential to determine culture-negative status. If a spontaneous sputum cannot be produced with ordinary nursing measures that promote sputum production, sputum induction X 3 is expected	The standard protocol is three consecutive culture negative sputum specimens. If three unsuccessful sputum <i>induction</i> attempts have been made and documented, public health does <i>not</i> require a bronchoscopy.
To establish culture conversion after treatment completed for active resp. dis. not previously documented. Examples: 1.) Culture conversion documented at 2 mo. followed by DOT, with improvement. 2.) MDR TB: Monthly sputums to monitor for relapse	Spontaneous or induced sputum is essential to determine culture negative status at the end of treatment if not confirmed earlier by three negative sputum cultures. If a spontaneous sputum cannot be produced with assistance, induce X 3.	The standard protocol is three consecutive culture negative sputum specimens. If three unsuccessful sputum <i>induction</i> attempts have been made and documented, public health does <i>not</i> require a bronchoscopy.

FREQUENTLY ASKED QUESTIONS on SPUTUM SPECIMENS

9. Are there some circumstances that should alert me to the need for sputum specimens when they are not part of the “routine”?

This will vary according to what clinical questions need to be answered. Sputum smears, MTD tests and cultures are done to determine infectiousness and to establish positive or negative culture status. Use sputum testing to determine if there are tuberculosis organisms in the respiratory system and/or whether the person is likely to be infectious or probably not infectious. Interrupted, incomplete, inadequate treatment or possible non-adherence to therapy requires a comprehensive clinical evaluation. Judgments should err on the side of caution related to length of treatment gap, risk factors, etc.

Clinical Circumstances Indicating the Need for Sputum Specimens	Sputum Specimens Positive	Sputum Specimens Negative
<p>Conflicting clinical picture - Any one or more circumstances that make you hesitate to rule out active TB without looking further, such as</p> <ul style="list-style-type: none"> ❑ Cough illness, undiagnosed respiratory symptoms, hemoptysis history, fever of unknown origin ❑ Any medical or population risk factors ❑ PPD result inconclusive or pending ❑ CXR report has inconclusive findings, or report describes nodules, cavitation, infiltrates, unclassified pneumonia, etc. ❑ Any clinical, radiological or laboratory findings that just don't fit together with the picture of the person 	<p>Collect three sputum specimens on three consecutive days to establish more clinical evidence when available data and clinical picture are in conflict. Smear positive - assume TB and assume infectious until TB is eliminated or successfully treated. Proceed with “work-up”, respiratory precautions, rapid MTD testing, cultures, chest x-ray, etc. Expert consultation for second opinions is often helpful. The MTD test rapidly identifies the <i>M. tb</i> RNA</p> <p>Use guideline charts and algorithms in Section C., Accessing Services and Resources Guideline</p> <p>Treatment decisions should be based on level of clinical suspicion of tuberculosis.</p>	<p>Three negative smears, probably not infectious, if clinical picture does not give other indications of infectiousness.</p> <p>Await culture reports before confirming that active TB is eliminated.</p>
<p>Interruption in medication regimen for a person with active disease* has been discovered, such as</p> <ul style="list-style-type: none"> ❑ Confirmation/suspicion of not taking all the pills ❑ Treatment regimen was incorrect; under-treated, malabsorbing, organisms not susceptible, etc. ❑ Non adherence to regimen is suspected or possible (not on DOT, missed DOT doses, partial DOT, etc.) ❑ Other factors for potential disease progression. (now HIV +, previously HIV -, diabetes uncontrolled, renal dialysis, other medical crisis) 	<p>Circumstance will vary according to how ill the person is, how much of a TB burden was/is present, how long they were without adequate treatment, and so on. Circumstances may dictate "starting over".</p> <p>At a minimum:</p> <p>Three sputum specimens are essential to establish infectious status for the person with interrupted, incomplete or possible non-adherence to treatment, especially if symptomatic or if disease progression is suspected. (Medical evaluation and chest x-ray also indicated.)</p>	<p>Three negative smears - probably not infectious</p> <p>Await culture reports before confirming that active TB disease is back under appropriate treatment/control</p>
<p>Interruption of medication regimen - a person with LTBI*</p> <ul style="list-style-type: none"> ❑ Confirmation/suspicion of not taking all the pills ❑ Risk factors for progression to active disease <p>* Interrupted, incomplete, inadequate treatment or possible non-adherence, <i>disease or infection</i> requires a comprehensive clinical evaluation. Judgments should err on the side of caution related to length of treatment gap, risk factors, etc. CXR/medical eval. may be indicated.</p>	<p>Three sputum specimens are definitely indicated for the symptomatic person and will be helpful in establishing infectious status for anyone with interrupted, incomplete or possible non-adherence to treatment. Sputum specimens are especially valuable if the chest x-ray or the medical evaluation is not complete. Smear positive status indicates beginning a new work up for active disease. Use MTD results if possible. Culture positive - proceed with treatment for active disease.</p>	<p>Three negative smears; probably not infectious, proceed to re-treat for LTBI. Await culture reports before confirmation that active TB disease has been eliminated.</p>

ENSURING PROMPT, ACCURATE SPUTUM TESTING

10. How should a sputum specimen be collected?

A model procedure for sputum collection is included in the guideline "Ensuring Prompt, Accurate Sputum Testing", available on the Wisconsin TB Program Web Site. Specialized testing and the interpretation of sputum results is outlined in **Section C., Accessing Wisconsin State Laboratory of Hygiene Services** the ACCESSING SERVICES AND RESOURCES for Persons with Suspect or Active Tuberculosis Disease or Latent Tuberculosis Infection (LTBI). This section of the guideline contains detailed information on handling, processing, and transporting specimens and in **how to interpret and use sputum test results.**** Ordering information for a free induction procedure model, "Conducting Sputum Induction Safely" from the Francis J. Curry National TB Center is also in the appendix of the sputum testing guideline.

11. What part should "standing physician's orders" play in this process, or what should our "standard protocol" be for requesting physician orders for sputum specimens?

Standard protocols may be utilized and should address at least the clinical circumstances described in this document. **However, communication with physicians or their designees and with the Wisconsin TB Program on a regular basis is essential in order to ensure that each person receives care and treatment that meets accepted treatment protocols and standards of practice.** A sample letter that may be helpful for physician communication is included. Each person's clinical situation is unique, therefore, an individualized assessment is essential to ensure that the correct specimens, in the correct time frames are collected, processed and transported in order for the medical provider to establish and sustain the right treatment. Physicians and other licensed prescribers in a low incidence state like Wisconsin often have not had experience with active TB disease management and they may not be aware of the indication and protocols for sputum testing. Since the overall burden of TB has diminished, examinations for tuberculosis smears, cultures and sensitivities are no longer "routine" for a cough illness as was done in the past. Active tuberculosis in Wisconsin is often unrecognized, undiagnosed, untreated and unreported until **after** active disease has been present for a considerable period of time, sometimes months. Alert, vigilant health care professionals and public health staff can prevent this from happening by increasing the awareness of today's available sputum testing procedures, especially the rapid testing for the rRNA of *M. tuberculosis*.

12. Where can I find out more information about sputum specimens and interpreting results?

** www.dhfs.wisconsin.gov/dph_bcd/tb

Access the Wisconsin TB Program Web site and under the heading Quick Links, use the hyperlink for Guidelines for Establishing Effective Policies, Procedures and Practices. The guideline that will provide you with the most sputum testing information is entitled ACCESSING SERVICES AND RESOURCES for Persons with Suspect or Active Tuberculosis Disease or Latent Tuberculosis Infection (LTBI). **Section C., Accessing Wisconsin State Laboratory of Hygiene Services** contains detailed information on the processes of AFB (Acid-Fast Bacilli) Testing, followed by information on the rapid testing process. The NAA (Nucleic Acid Amplification) testing done is called Mycobacterium Tuberculosis Direct (**MTD**). Following the information about the tests is detailed information about **how to correctly interpret and utilize the results**. Also included here is very specific information about handling and processing, as well as the express transportation available. This is a process-oriented guideline that takes the reader through all the necessary steps needed in order to ensure prompt, accurate results. For additional questions, call the Wisconsin TB Program at 608-266-9692 or the Wisconsin State Laboratory of Hygiene at 608-262-1618.

ENSURING PROMPT, ACCURATE SPUTUM TESTING

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ENSURING PROMPT, ACCURATE SPUTUM TESTING

Ordering Information for the booklet:

Conducting Sputum Induction Safely

Appendix A of this booklet contains a **detailed procedure for sputum induction** that can be followed if there is no written procedure available.

It also describes administrative and engineering controls and respiratory protection needed if staff intend to induce sputum specimens in a TB Services Clinic or similar setting.

These engineering requirements do not apply to collection of sputum specimens in the home, however, **proper respiratory precautions and the use of personal protective equipment (PPE)** is to be implemented by health department staff when indicated for the person who is **infectious or potentially infectious**.

Ordering information is available on the Web site of the Francis J. Curry National Tuberculosis Center:

www.nationaltbcenter.edu

There is also a Quick Link on the Wisconsin TB Program Web page to the National TB Center
Click on the National Center's Site Map,
then click on **Workplace Tools**

You may also send an e-mail request to

tbcenter@nationaltbcenter.edu

or order by phone or fax at:

Phone # (415) 502-4600

Fax # (415) 502-4620

The product that should be requested is:

Conducting Sputum Induction Safely

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